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TI **Preparation of solid rapidly disintegrating dosage form with reduced friability - by overfilling mould with aqueous composition, freezing and removing solvent**
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IN LAWERENCE J; LAWRENCE J; POSAGE G; POSAGE G W; MAKINO T; MASUDA A; OKADA G
PA (JANC-C) JANSSEN PHARM NV; (MURA-C) MURATA MFG CO LTD
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PI

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IPCI A61J0003-10 [I,A]; A61J0003-10 [I,C]; A61K0031-519 [I,A]; A61K0031-519 [I,C]; A61K0009-20 [I,A]; A61K0009-20 [I,C]; A61K0009-20 [I,C]

IPCR A61K0031-445 [I,A]; A61K0031-445 [I,C]; A61K0031-4465 [I,A]; A61K0031-4465 [I,C]; A61K0031-4468 [I,A]; A61K0031-4468 [I,C]; A61K0009-20 [I,A]; A61K0009-20 [I,C]; A61K0009-44 [I,A]; A61K0009-44 [I,C]

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Preparation of solid rapidly disintegrating dosage form (SDF) comprising a porous network of matrix forming materials (MFM) comprises: (a) overfilling a mould with a predetermined amount of aqueous composition comprising MFM so that a convex meniscus is created on top of the mould; (b) freezing; and (c) removing the solvent by subjecting the product to lyophilisation or to solid state dissolution leaving a porous network of MFM. The shape of the bottom surface of the mould is a mirror image of the shape of the frozen meniscus on the top, the mirror plane being parallel to the plane defined by the rim of the mould, yielding a dosage form shaped as a biconvex tablet, having symmetrical top and bottom surfaces. The SDF prepared as above is claimed per se. Also claimed is a metal or plastic sheet for use in the above process for preparing dosage forms shaped as biconvex tablets having symmetrical top and bottom surfaces comprising moulds arranged in a regular pattern, the shape of the bottom surface of each mould being a mirror image of the shape of a predetermined convex meniscus on the top, the mirror plane being parallel to the plane defined by the rim of the mould.

ADVANTAGE - The solid form disintegrates rapidly and has reduced friability as a result of less acute angles between side walls or walls and top or bottom surfaces. The symmetry also means that there is no distinction between the top and bottom of the dosage form once it is removed from its mould and the biconvex shape can be picked up easily and can be arranged to lie on one of the convex surfaces by gently shaking. - The shape also serves to distinguish them from prior art dosage forms and may assist in preventing errors by physicians, pharmacists and end-users.

FS CPI; GMPI

MC CPI: A12-V01; B04-C03B; B11-C09; C04-C03B; C04-C03B; C11-C09; C11-C09